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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,180	08/03/2001	Chiaki Senoo	50026/027001	1189
21559	7590	02/13/2007		
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			EXAMINER SWOPE, SHERIDAN	
			ART UNIT	PAPER NUMBER
			1652	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/13/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

09/831,180

Applicant(s)

SENOO ET AL.

Examiner

Sheridan L. Swope

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 November 2006 and 10 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 9-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-8 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>1106</u> . | 6) <input type="checkbox"/> Other: _____  |

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**DETAILED ACTION**

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1652. Applicants' responses of November 27, 2006 and January 10, 2007, to the action mailed May 23, 2006, are acknowledged. It is acknowledged that Claims 1, 2, 4-9, and 11 have been amended and Claim 15 has been canceled. Claims 1-14 are pending. Claims 9-14 were previously withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions. Claims 1-8 are hereby reexamined.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

***Utility***

Rejection of Claims 1-8 under 35 U.S.C. 101/112 because the claimed invention lacks patentable utility, for the reasons explained in the prior action, is maintained. In support of their request that said rejection be withdrawn, Applicants provide the following arguments.

(A) Example 10 of the Utility Guidelines describes a specification disclosing a novel protein, which demonstrates a high level of homology to a DNA ligase. Relevant thereto, the Guidelines state that "based on applicant's disclosure and the results of the PTO search, there is no reason to doubt the assertion that SEQ ID NO: 2 encodes a DNA ligase. Further, DNA ligases have a well-established use in the molecular biology art based on this class of protein's ability to ligate DNA. The present invention is directed to polypeptides of the family of trypsin-like serine proteases. The recited Tespec PRO-2 polypeptide includes two signature protease

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motifs; the “trypsin-his” and “trypsin-ser” motifs. Figure 3 further shows the alignment of Tespec PRO-2 polypeptide with several known trypsin-family protease, such as acrosin, prostatin, and trypsin. Thus, based on the Utility Guidelines and the instant specification, Tespec PRO-2 polypeptide has utility as a trypsin-family protease.

(B) Applicants’ enclosure (Appendix A), provides evidence that PROSITE teaches that “if a protein includes both the serine and histidine active site signatures, the probability of it being a trypsin family serine protease is 100%” (Brenner, S., 1988, *Nature*, 334: 528-530; Rawlings, N. D. and Barrett, A. J. (1994) *Meth. Enzymol.*, 244: 19-61). Therefore, it can be concluded that Tespec PRO-2 polypeptide is a trypsin family serine protease.

These arguments are not found to be persuasive for the following reasons.

(A) Reply: Example 10 of the Utility Guidelines describes a specification disclosing a novel protein, which demonstrates 95% homology to a known DNA ligase. Said specification is not homologous to the instant specification: the protein of SEQ ID NO: 2 does not have high homology to any protein with a demonstrated specific and substantial activity. For example, while it is well-known that trypsin has a specific and substantial activity as a gastrointestinal protease, SEQ ID NO: 2 does not have high homology to trypsin. Likewise, SEQ ID NO: 2 does not have high homology to either prostatin or acrosin, whose functions are yet to be even discovered (Tucker et al, 2005; Moreno et al, 2006). Therefore, a specific and substantial utility for the polypeptide of SEQ ID NO: 2 cannot be deduced based on high homology to any protein with a well-established function. Also see (B), below.

(B) Reply: It is acknowledged that Applicants’ arguments provide evidence that their Tespec PRO-2 polypeptide is a trypsin-family protease. However, evidence as a trypsin-family

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protease is not evidence of a specific and substantial, patentable utility. As acknowledged by Applicants in their instant enclosure (Appendix A, page 1), the trypsin-family is a large and variable family comprising proteases having a large number of variable substrates and the potentiality of being involved in many different cellular processes and diseases. The specification fails to provide evidence, or even assert, that the polypeptide of SEQ ID NO: 2 has the utility of any specific trypsin-like protease.

For these reasons and those explained in the prior action, rejection of Claims 1-8 under 35 U.S.C. 101/112 because the claimed invention lacks patentable utility is maintained.

Applicant's amendment necessitated any new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Regarding filing an Appeal, Applicants are referred to the Official Gazette Notice published July 12, 2005 describing the Pre-Appeal Brief Review Program.

**Final Comments**

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To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

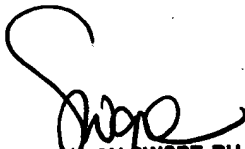
It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheridan Lee Swope, Ph.D.  
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**SHERIDAN SWOPE, PH.D.**  
**PRIMARY EXAMINER**